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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,703	05/01/2001	Mark W. Kroll	A01P1028	6988

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PACESETTER, INC.  
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Sylmar, CA 91392-9221

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/847,703

Applicant(s)

KROLL, MARK W. *CM*

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to because figures 3 and 4 appear to be redundant. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

2. The brief description of the drawings is confusing because on page 11 of the specification, there are two descriptions of figure 4 and no description of figure 3. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5, 7, 18, 27 and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nerboven-Nelissen (US 5720768) (abstract; figure 5A; c 2, ll 13-21; c 2, ll 31-44; c 3, ll 48-50 and 54-59; c 3, l 66 - c 4, l 2; c 4, ll 38-44; c 4, ll 65-67; c 5, ll 23-35; c 6, l 61 - c 7, l 5)

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5. Claims 1-3, 5, 7-15, 18-24 and 27-28 rejected under 35 U.S.C. 102(e) as being anticipated by Yerich et al. (US 6456878). Yerich et al discloses the claimed invention (c 3, 18-65; c 4, ll 29-48; c 5, ll 22-47; c 6, ll 8-11, 16-20, 31-35 and 39-43; c 6, l 61 – c 7, l 43; c 7, ll 50-61; c 8, ll 14-39; c 10, l 52 – c 11, l 10; c 11, ll 15-33; c 12, ll 7-25; c 13, ll 26-30 and 42-45; c 15, ll 32-47; c 16, ll 9-24; c 18, ll 1-12)

As related to claims 1, 18 and 27, the stimulation is a cross-chamber configuration (c 8, ll 14-29; c 15, ll 38-44).

As related to claims 2 and 22, pacing between tip electrodes is disclosed, but is undesirable because of the smaller stimulation surface area (c 15, ll 38-44).

As related to claim 7, the sensing is between two right ventricular electrodes (c 7, ll 38-43).

As related to claims 8, 9, 12 and 22, sensing occurs using a cross-chamber configuration between an electrode pair that is different than the pacing electrode pair. While sensing and pacing are disclosed using the left ventricle tip electrode (50), additional electrodes may be added to the left ventricle lead, such as a left ventricular ring electrode, to enable alternate electrode configurations such that the pacing pairs and sensing pair are different (c 8, ll 14-29; c 10, l 65 – c 11, l 10; c 11, ll 20-33; c 15, ll 32-47).

As related to claim 10, the vectors are read as directional pathways (c 16, ll 9-24).

As related to claim 13, 14, 23 and 24, pacing is disclosed in the right/left chamber and sensing occurs in the opposite chamber (right/left chamber). While sensing and pacing are disclosed using the left ventricle tip electrode (50), additional electrodes may be added to the left ventricle lead, such as a left ventricular ring electrode, to enable

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alternate electrode configurations such that the pacing occurs in one chamber and the sensing occurs in the other chamber (c 8, ll 14-29; c 10, l 65 – c 11, l 10; c 13, ll 26-30 and 41-45; c 15, ll 32-47).

As related to claim 15, the sensing occurs between the left atrial electrode and the right ventricular electrode (c 8, ll 30-39; c 12, ll 15-20)

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 4, 16, 17, 25, 26, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yerich et al. (US 6456878) in view of Condie et al. (US 5902325). As discussed in paragraph 5 of this action, Yerich et al. discloses the claimed invention except for a biphasic pulse applied to the left and right ventricle (claim 4 and 6) and

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verifying capture by detecting an evoked response or a delay and an intrinsic response (claims 16, 17, 25, 26, 29 and 30).

Condie et al. teach a capture detection system using biphasic pulses for the purpose of canceling electrode polarization (c 9, l 61 – c 10, 3; c 12, ll 20-25). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used biphasic pulses in the Yerich et al. system in order to avoid long-term lead metal-ion oxidation caused by monophasic pulses (c 13, ll 60-67).

Condie et al. teach a capture detection system that verifies capture by detecting, immediately following the stimulation, an evoked response or a sequence of time delay and an intrinsic response for the purpose of clearly detecting successful cardiac depolarization (c 14, ll 25-62; c 16, ll 7-26). It would have been obvious to one having ordinary skill in the art at the time of the invention to have verified capture by detecting, immediately following the stimulation, an evoked response or a sequence of time delay and an intrinsic response as in the Yerich et al. system in order to reliably detect capture to prolong battery life and avoid unnecessary, potentially dangerous stimulation treatment (c 4, ll 10-18; c 16, ll 14-16).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*JPO*  
*12/13/02*

*[Signature]*  
JEFFREY R. JASTRZAB  
PRIMARY EXAMINER

*3763*  
*12/6/02*